

Instructions for use



OsseoSet™ 200

SI-923 / SI-915

W&H Symbols



WARNING!
(Risk of injury)



ATTENTION!
Important notes!
(to prevent damage occurring)



General explanations,
without risk to
persons or objects



Thermo washer disinfectable



Sterilizable
up to the stated temperature



W&H Service

Only for USA

Caution: Federal law restricts this device to sale by or on the order of a dentist, physician or any other practitioner licensed by the law of the state in which he or she practices to use or order the use of the device.

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1. Introduction



For your safety and the safety of your patients

These Instructions for Use explain how to use your OsseoSet™ 200. However, we must also warn against possible hazardous situations. Your safety, the safety of your team, and of course, the safety of your patients are of paramount importance to us.



It is therefore essential to read the safety notes on Pages 8 to 11.

Intended use

Mechanical drive unit with coolant supply for transmission instruments with coupling system according to ISO 3964 (DIN 13.940).

The equipment is a drive unit for use in dental surgery, implantology and maxillo-facial surgery for treatment of dental hard tissue.

Qualifications of the user

Only suitably qualified medical, technical and specialist trained staff may use the dental surgical unit OsseoSet™ 200. We have based our development and design of the OsseoSet™ 200 on the "physician" target group.

Introduction

 **Production according to EU Directive**
0297 EU Directive 93/42/EEC has been used as a basis in the design and manufacture of this medical product and this applies to the dental surgical units

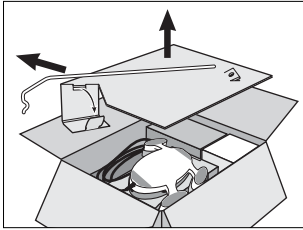
- OsseoSet™ 200 SI-915 and
- OsseoSet™ 200 SI-923

in the condition as supplied by us. This declaration does not apply to non-specified fittings, mountings etc.

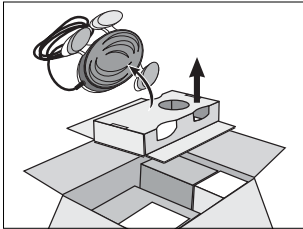
 **Responsibility of the manufacturer**
The W&H Dentalwerk (dental factory) in Bürmoos can only accept responsibility for the safety, reliability and performance of the OsseoSet™ 200 when there is compliance with the following directions:

- OsseoSet™ 200 must be used in accordance with these Instructions for Use.
- OsseoSet™ 200 has no components which can be repaired by the user. Assembly, modifications or repairs must only be undertaken by skilled personnel authorized by W&H.
- The electrical installation at the premises must comply with the regulations of ÖVE-EN 7 ("Installation of electrical equipment in rooms used for medical purposes") or with the regulations applicable in your country.
- Unauthorized opening of the equipment invalidates all claims under warranty and any other claims.

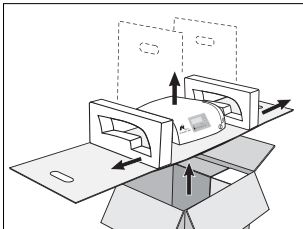
2. Unpacking



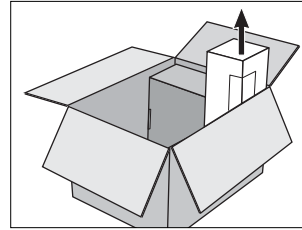
1 Lift out insert with stand.



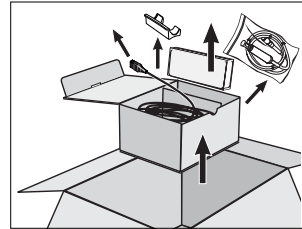
2 Remove foot control and insert.



3 Lift out insert with control unit.



4 Remove carton with mains cable.



5 Remove carton containing motor, motor support, drill gauge, locking pins and instrument.

The packaging is environmentally friendly and can be disposed of by industrial recycling companies.

However, we recommend that you keep the original packaging.

3. Equipment supplied

- Control unit REF NB05018200 (230 V)
- Foot control S-NU 1, REF NB04491600
- Motor with 1.8 m cable including 5 clips, REF NB04720016
- Mains cable REF NB01343700 (Europe) / REF NB03212700 (UK, IRL) / REF NB02909300 (AUS, NZ)
- Motor support REF NB05028500
- Stand REF NB04005900
- Locking pins REF NB04006800 (2 pcs)
- Clips REF NB04019000 (5 pcs)
- Drill gauge REF NB02139800
- Contra-angle handpiece

Alternative specification:

- Control unit REF NB05018300 (115 V)
- Mains cable REF NB02821400 (USA, CAN, J)

4. Safety notes



Please ensure that you carry out the following instructions

- Only fit the handpieces when the motor is at a complete standstill.
- Never touch rotary instruments which are still rotating.
- Never touch the chuck mechanism of straight and contra-angle handpieces while they are still running.
- Always ensure correct operating conditions and that sufficient and adequate cooling is delivered.
- Avoid overheating at the treatment site.



Use only suitable and serviceable tools

Ensure that you comply with the manufacturer's instructions for surgical straight and contra-angle handpieces with respect to maximum speed, maximum torque, forward and reverse movement.



Inappropriate use

Improper use, in addition to incorrect assembly, installation, modification or repairs of the OsseoSet™ 200 or non-compliance with our instructions invalidates all claims under warranty and any other claims.

Cardiac pacemaker function

Use of the OsseoSet™ 200 involves the generation of magnetic fields, which are below the interference threshold limit according to EN 50061 Ad1. Even under adverse conditions, there is no likelihood of serious harm to the patient. The OsseoSet™ 200 is designed for the intermittent operating mode S3 with an operating time of 4 minutes and a pause time of 10 minutes.

Safety notes



Danger zones M and G

In accordance with IEC 60601-1 / UL 60601-1, the control unit is not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anaesthetic substances containing oxygen or nitrous oxide.

Control unit

The control unit is classed as "conventional equipment" (closed equipment without protection against the ingress of water).



The OsseoSet™ 200 Programs 4 and 5 are only designed to be used with the contra-angle handpieces WI-75 E/KM and WS-75 E/KM approved by W&H. Use of other contra-angle handpieces may result in deviation from the indicated torques and is under the user's responsibility. The specified transmission ratios for the Programs 1 to 5 must always be considered.



Motor and foot control

The motor and foot control are approved for use in zone M (AP).

Please note that at low speeds, it is more difficult to determine that the motor is running.

Safety notes

Mains cable

Only connect to an earthed socket outlet.

Power failure

In the event of a power failure, if the OsseoSet™ 200 is switched off, or when alternating between programs, the last values set are saved and re-activated on power-up.

System failure

A total system failure of the OsseoSet™ 200 does not constitute a critical fault.

Intermittent operating mode S3 (4min/10min)

When there is a current consumption of max. 0.8 A for SI-923 and 1.6 A for SI-915 (with pump switched on), the permissible relative load time is 4 minutes to 10 minutes pause time.

Safety notes



Coolant

The OsseoSet™ 200 is designed for use with physiological saline solution. Use only suitable irrigation fluids and comply with the medical data and instructions from the manufacturer. Coolant bottle, coolant bag and sterile fittings can be obtained from a pharmacist.



Rotational energy

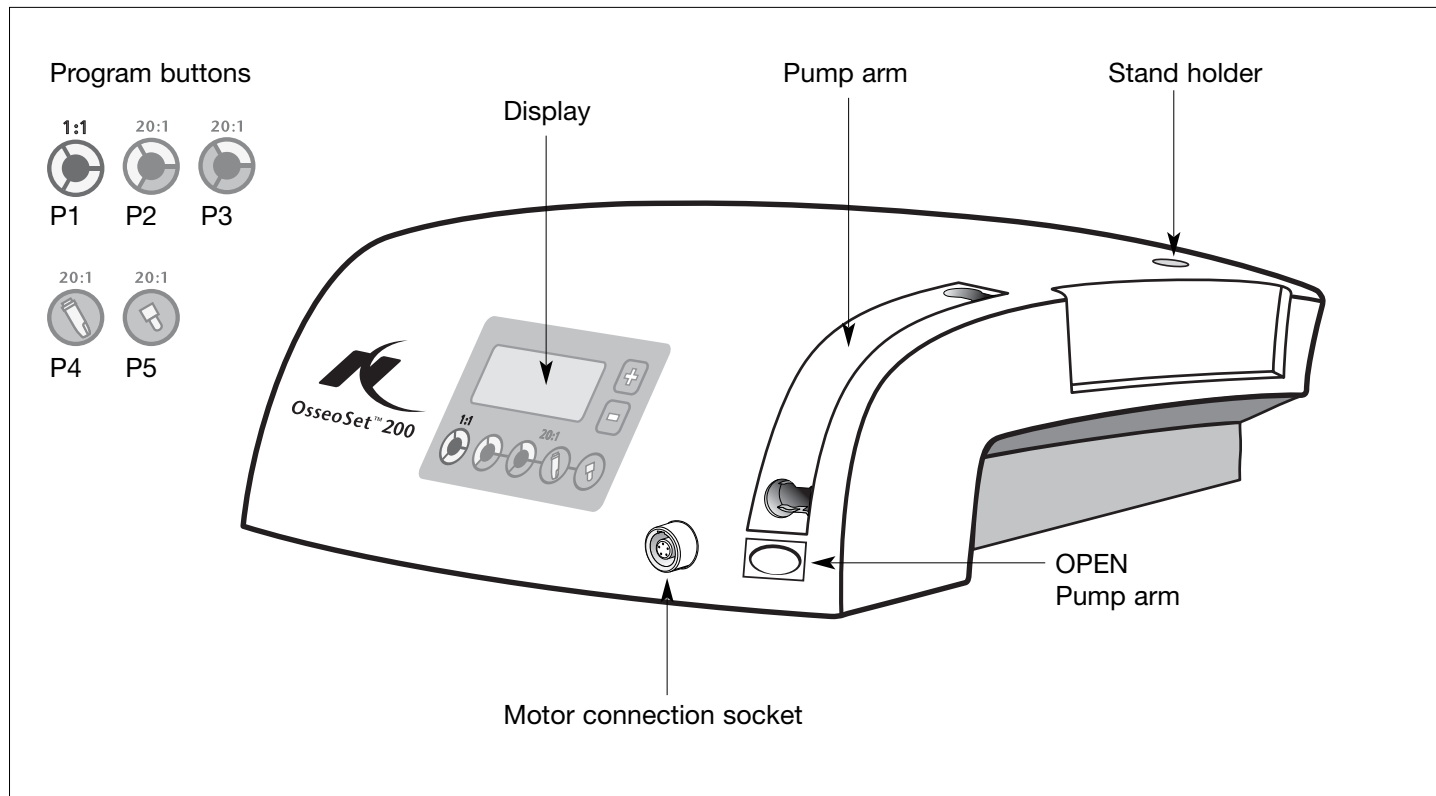
Fast deceleration of the bur can, at times, cause the selected torque to be overloaded as a result of the rotational energy stored in the drive system.

We therefore advise compliance with the individual manufacturer's instructions for use, particularly when adjusting superstructure screws.

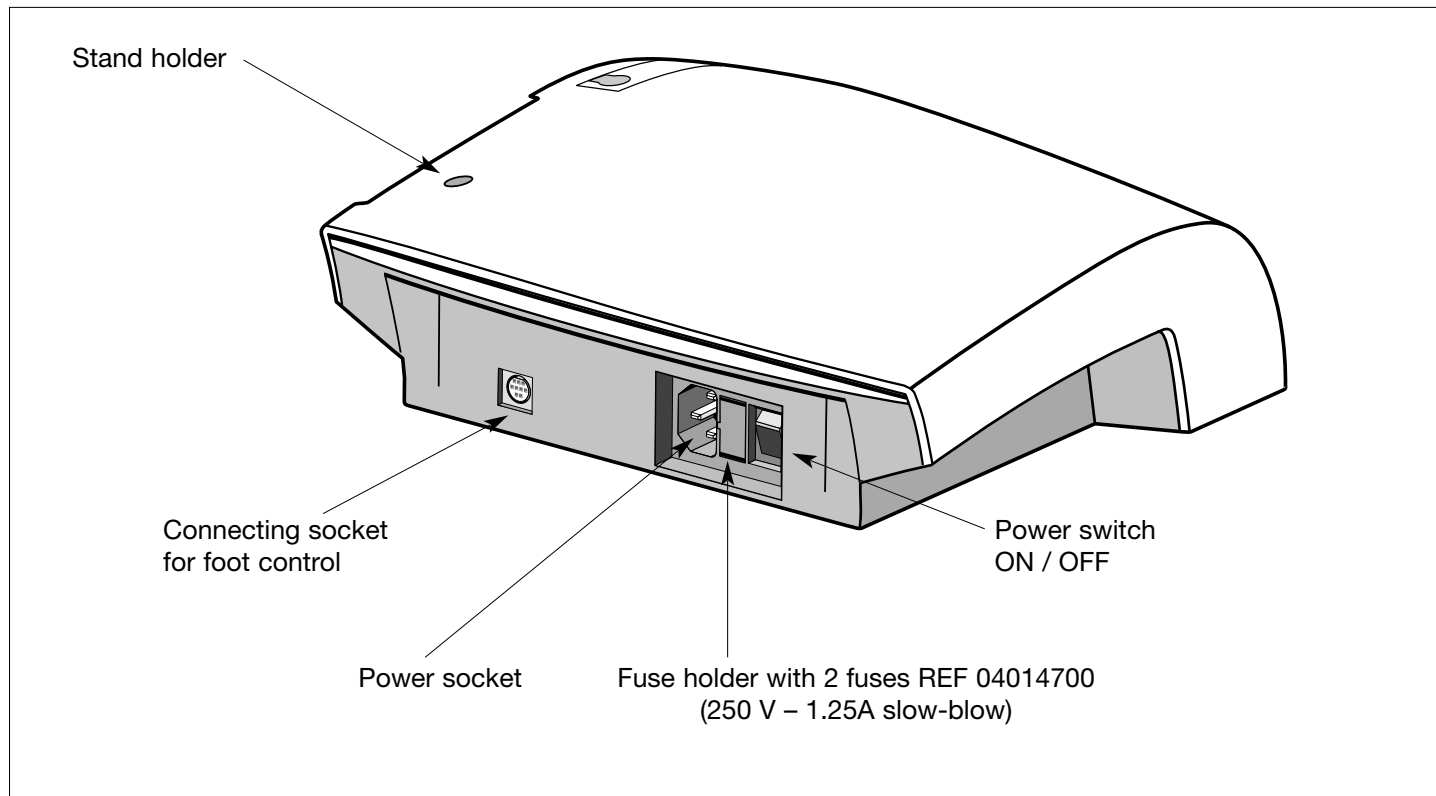
For safety reasons, these should be screwed in very carefully by hand, or by using a torque wrench.

We would point out that adjusting these screws with an electric motor represents a potential risk as described above.

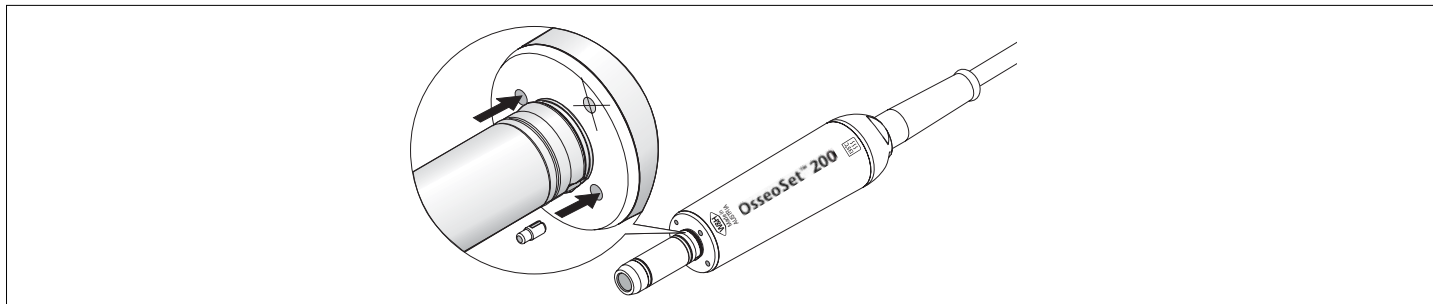
5. Description of front panel



6. Description of rear panel



7. Description of motor with cable



The motor may not be dismantled!

The motor bearings are lubricated for life. No oil lubrication or other maintenance is necessary.

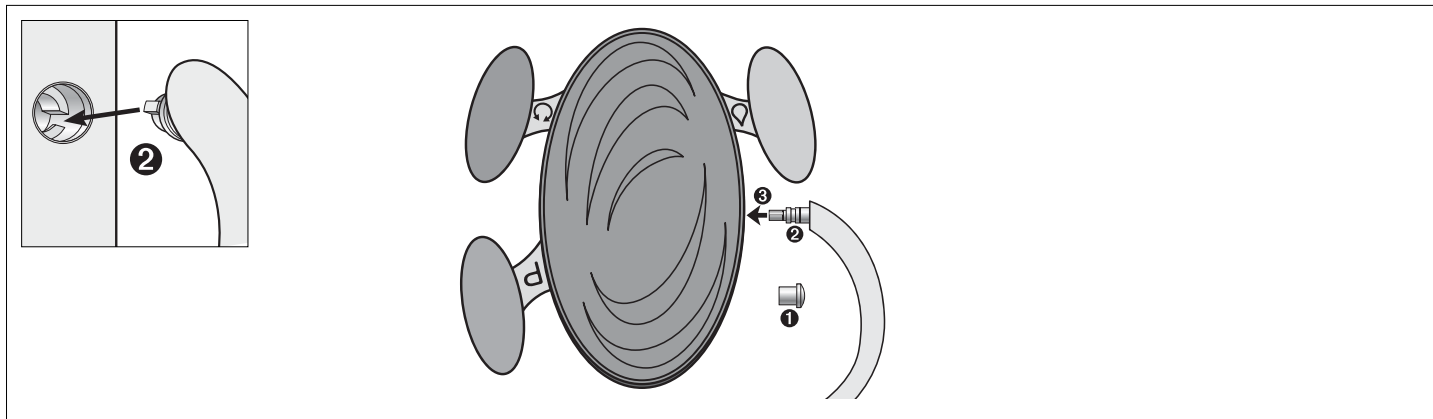


To prevent the instrument on the motor attachment from turning during the transmission, the locking pin supplied can be pushed into one of the two holes (see illustration). The locking pins can only be used in combination with straight and contra-angle handpieces that have corresponding holes.

Test run

- Start the motor.
- If you observe dysfunctions (e.g. vibrations, unusual noise, overheating, coolant supply failure or leakage) contact your authorized service organization (see Page 45 – 47).

8. Starting operation foot control – Fitting / Removing the handle



Fitting the handle

For easy fitting of the handle rotate the foot control by 180°.

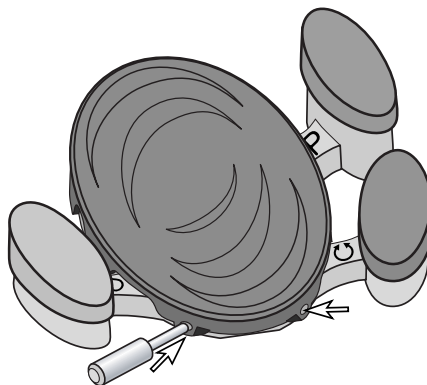
- ❶ Remove the protective cap from the handle hole.
- ❷ Locate the guide pin of the handle in the recess in the hole within the foot control.
- ❸ Press the handle until it audibly engages into the recess.

Swivel the handle upwards into the desired position.

Removing the handle

Turn the handle to the rear and pull out.

Starting operation foot control – Disassembly of foot control



Disassembly of foot control – removing the pedal for disinfection and cleaning (see Page 30)

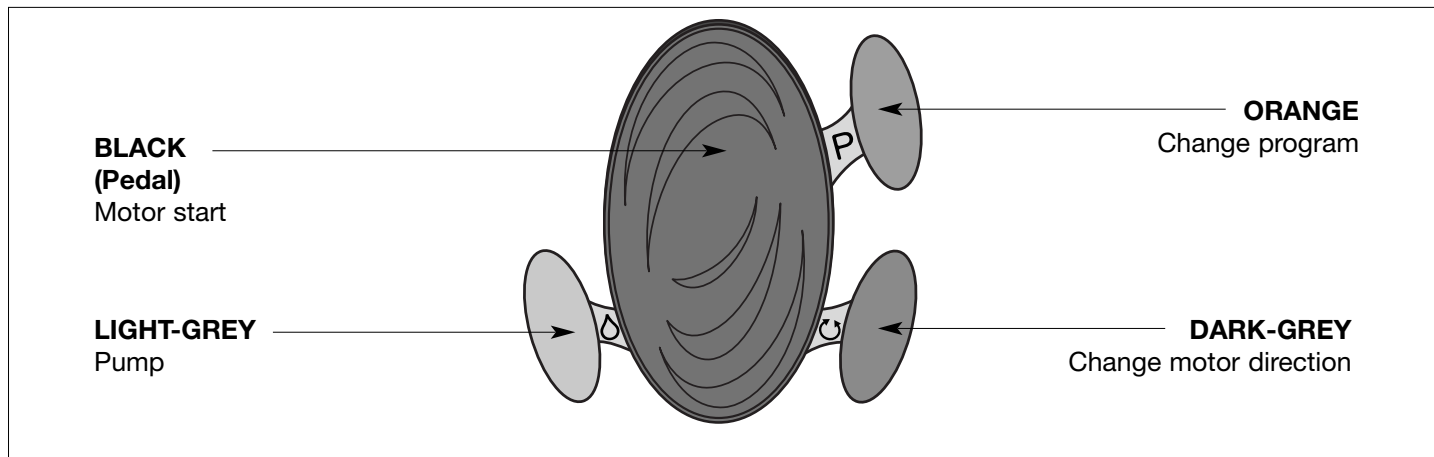
- Remove the handle from the foot control.
- Press on one of the two guide pins with the tool provided and lift the pedal slightly.
- Press on the second guide pin with the tool and remove the pedal.
- Take out and retain the springs.

Starting operation foot control – Reassembly of foot control



- Make sure that both springs are inserted in the appropriate recess.
- Position the pedal at the end of the foot control into the mounting plate.
- Press the two guide pins in front of the foot control at the same time and allow the pedal to engage.
- Refit the handle.

Starting operation foot control – Description of pedal



Function

BLACK	=	VARIABLE or ON / OFF (Factory setting = variable)
LIGHT-GREY	=	Pump ON / OFF
ORANGE	=	Program 1 to 5
DARK-GREY	=	Motor forward / reverse drive

Starting operation foot control – Description of pedal

Changing program

The Programs 1 – 5 can be selected in ascending sequence by operating the ORANGE button. When changing from Program 5 to Program 1, a longer confirmation signal is heard. With each program change, the speed is automatically set to forward operation.

Pump ON / OFF

Only when the motor is at a complete standstill can the pump be switched on or off by operating the LIGHT-GREY button of the foot control. When pump operation is active, the pump symbol appears on the display.

Reverse operation

You can switch between forward and reverse operation by pressing the DARK-GREY button. On selecting reverse operation, an audible signal can be heard and the selected Program button flashes. Before the motor starts in reverse operation, 3 audible warning signals are given.

Starting operation foot control – To change from **VARIABLE** to **ON / OFF**



Keep Program button P3 depressed throughout this procedure!



❶ Press P3 for approx. 4 seconds



❷ Keep P3 depressed and simultaneously press PLUS and MINUS



❸ Keep P3 depressed and carry out adjustment.

01 = VARIABLE (factory setting) – Press PLUS button

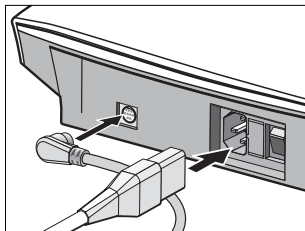


00 = ON / OFF – Press MINUS button

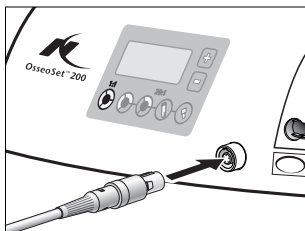


After changeover the Program button P3 illuminates and is active!

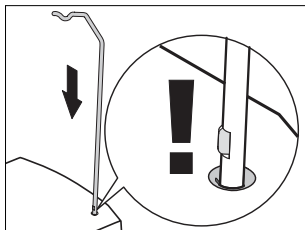
9. Starting operation – General



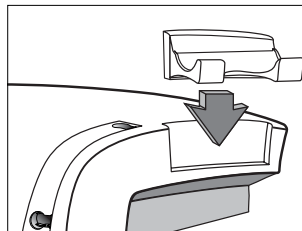
- ❶** Connect the mains cable and foot control.



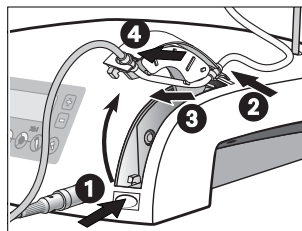
- ❷** Connect the motor cable.
 Note the positioning!



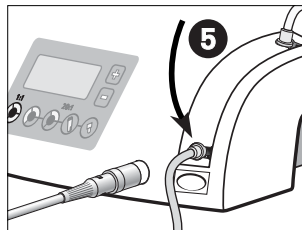
- ❸** Insert the stand.
 Note the positioning!



- ❹** Fit the motor support.



- ❺** Fit the irrigation tubing set.



- ❻** Close pump arm.

10. Reset factory settings



Factory setting always starts with Program 1 (P1).

- ❶ Switch off the control unit



- ❷ Keep P1 depressed and simultaneously switch on the control unit

- ❸ Keep P1 depressed as long as on the display the adjustment “DE FAU” appears

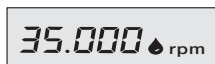
Factory settings (P1 – P5)

	P1 	P2 	P3 	
Transmission ratio	1:1	20:1	20:1	
Factory setting rpm	40 000	2 000	800	
Adjustable range rpm	300 – 40 000	15 – 2 000	15 – 2 000	
Motor direction	forward	forward	forward	
Pump	on	on	on	
Factory setting Ncm	max.	max.	max.	
Adjustable range Ncm	–	–	–	

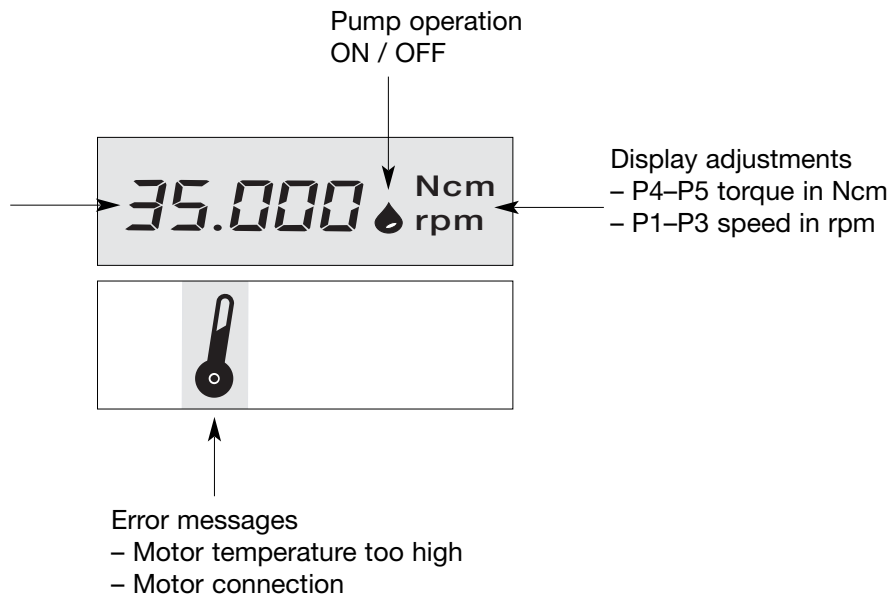
	P4 forward 	P4 reverse 	P5 forward 	P5 reverse 
Transmission ratio	20:1	20:1	20:1	20:1
Factory setting rpm	30	60	15	20
Adjustable range rpm	–	–	–	–
Motor direction	forward	reverse	forward	reverse
Pump	on	on	on	on
Factory setting Ncm	20	20	20	20
Adjustable range Ncm	5 – 50	5 – 50	5 – 50	5 – 50

11. Control unit operation – Changing the program (P1 – P5)

 Activate the required Program (P1 – P5) by pressing the corresponding Program button. During selection an audible signal can be heard and the Program button is illuminated. On the display the selected Program appears with the adjusted range in rpm, e.g. for P1:



Display adjustments
– P1–P3 speed
– P4–P5 torque



Control unit operation – Changing the speed (P1 – P3)



Keeping PLUS / MINUS depressed activates the repeat function and the values are continuously increased / decreased.

❶ Press Program button (P1–P3)



❷ Increase speed



❷ Decrease speed

Control unit operation – Changing the torque (P4 – P5)

 Adjustable range from 5 up to 50 Ncm. Keeping PLUS / MINUS depressed activates the repeat function and the values are continuously increased / decreased.

When changing from 5 to 50 Ncm and 50 to 5 Ncm, a longer confirmation signal is heard.

When the adjustable torque in the the forward/reverse drive mode is reached, the motor switches off automatically.

❶ Press Program button (P4, P5)



❷ Increase torque in 5-Ncm-steps



❷ Decrease torque in 5-Ncm-steps

Control unit operation – Changing the coolant flow (P1 – P5)



Factory setting 100 %. Adjustable range 65 %, 80 % and 100 %.
Depressing PLUS / MINUS the values are continuously increased / decreased.



Keep Program button P2 depressed throughout this procedure!



- 1 Keep P2 depressed for approx. 4 seconds
(the adjusted coolant flow rate appears)



- 2 Keep P2 depressed and press PLUS button
to increase flow rate



- 2 Keep P2 depressed and press MINUS button
to decrease flow rate



After adjustment, the Program button P2 illuminates and is active!

12. Error messages

Error No.	Description	Remedy
00	Electronics overheating – safety shutdown	Switch off the equipment, allow to cool for at least 10 minutes, then re-start
01	Electronics overloaded	Switch off the equipment and then re-start
07	Foot control error – initializing	Switch off the equipment, re-start, do not actuate foot control when switching on
09	Foot control error	Switch off the equipment, check connection of the foot control, then re-start
19	Run limiting control	Switch off the equipment and re-start
99	System failure	Switch off the equipment and re-start
	Motor temperature too high	Switch off the equipment, allow motor to cool for at least 10 minutes, then re-start
	Motor connection – safety shutdown	Switch off the equipment, check motor connection, then re-start

Error messages



If one of the error messages described above cannot be rectified by switching off the OsseoSet™ 200 and then switching it on again, the equipment must be checked by a service and repair organization authorized by W&H (see Page 45 – 47).

If a total failure of the equipment occurs caused by external circumstances, the equipment must be switched off and then on again.

13. Disinfection, Cleaning, Sterilization



- Wear protective gloves.
- Disinfect and clean the motor **immediately after every treatment!**
- Sterilize the motor following disinfection and cleaning.
- Motor with cable and motor support must be sterilized prior to every use.

Control unit, foot control, handle

Manual disinfection and cleaning



The front panel of the control unit is sealed and may be wiped clean.

- Remove handle from the foot control.
- Remove pedal from the foot control (see Page 16).
- If heavily soiled: Clean first with disinfectant cloths.
- Disinfect using surface disinfectants; spray disinfection is recommended.
- Use certified surface disinfectants (e.g. DGHM-tested). **For USA:** Use EPA registered surface disinfectants.
- Note the action times of the disinfectants used!
- Reassembly of foot control (see Page 17).

Disinfection, Cleaning, Sterilization

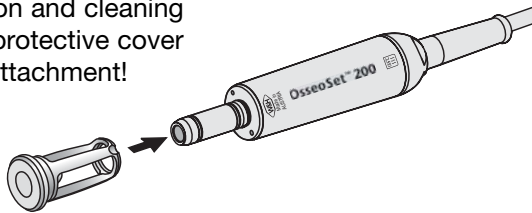
Motor with cable



Do not twist and kink the motor cable! Do not coil it too tightly!



Before disinfection and cleaning push the motor protective cover onto the motor attachment!



Manual disinfection

- If heavily soiled: Clean first with disinfectant cloths.
- Disinfect using surface disinfectants; spray disinfection is recommended.
- Use certified surface disinfectants (e.g. DGHM-tested). **For USA:** Use EPA registered surface disinfectants.
- Note the action times of the disinfectants used!

Manual cleaning

- Rinse under demineralized water (< 38 °C) with the aid of a brush (not recommended in U.K.)
- Then remove any liquid residues (absorbent cloth, blow dry with compressed air)

Disinfection, Cleaning, Sterilization

Sterilization and storage

- Note the instructions of the unit manufacturer.
- Only sterilize cleaned motors and accessories.
- Wrap motors and accessories in sterile goods packing according to EN 868-5.
- Store sterile goods dust-free and dry.



W&H recommends sterilization according to EN 13060, class B

Permitted sterilization methods

Vacuum sterilization – Remove the motor protective cover!

Steam vacuum sterilization according to EN 13060, using a sterilization holding time of a minimum of 3 minutes at 134 (+ 3) °C (273.2 + 5.4 °F)

or

Gravity sterilization – Remove the motor protective cover!

Steam gravity sterilization using a sterilization holding time of a minimum of 4 minutes at 134 (+ 3) °C (273.2 + 5.4 °F)



For sterilization in sterilizers without a drying program we recommend you to use the motor protective cover (see Page 31).



Before starting operation again

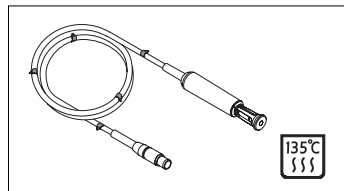
Wait until the motor and cable are completely dry.

Moisture in the plug or motor can lead to a malfunction! (Risk of short circuit)

14. Accessories

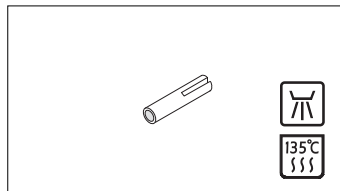
Use only original W&H accessories/spare parts
or accessories approved by W&H

For spare parts and other accessories not listed here,
please contact your local W&H representative or service station.



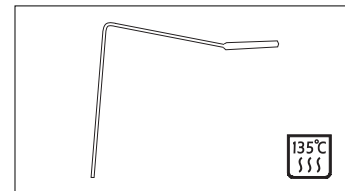
NB04720016

Motor with 1.8 m cable



NB04006800

Locking pin



NB02610500

Cannula for internal bur cooling



NB10207554

Contra-angle handpiece
WI-75 E/KM, 20:1



NB10207513

Contra-angle handpiece
WS-75 E/KM, 20:1



NB00001104

Straight handpiece
S-11, 1:1

15. Servicing



Regular checking of OsseoSet™ 200 and accessories

Regular servicing of function and safety of the OsseoSet™ 200 including the accessories is necessary and should be carried out at least once every three years, unless shorter intervals are prescribed by law. The inspection must be undertaken by a qualified organization and needs to include the following procedures:

- visual inspection for outside damage
- measurement of enclosure leakage current
- measurement of patient leakage current
- visual inspection of internal components and electronic boards on suspicion of safety interference,
e. g. mechanical damage of the enclosure or indicators for overheated or burned (electronic) components

We recommend that only skilled personnel authorized by W&H should undertake this servicing and checking.

Servicing

Motor and cable

The standard ISO 11498 stipulates a durability of at least 250 sterilization cycles. In the case of the motor and cable from W&H, regular servicing is specified only after 500 sterilization cycles, or one year.

Repairs

If a defect occurs, always return all the equipment, due to the fact that with motor malfunctions, an inspection of the electronic controls is also necessary!

Returns

- Refer all questions to your authorized dental dealer or to one of our service organizations (see Page 45 – 47).
- Always return equipment in the original packaging!
- Always include description of error and a copy of purchase invoice!
- Do not coil the cable around the motor and do not twist or kink the motor cable! (Risk of damage)

16. Technical data

OsseoSet™ 200

Supply voltage:
 Rated current:
 Permitted voltage fluctuation:
 Frequency:
 Max. mechanical output power:
 Max. torque on the motor:
 Max. coolant in ml (with hose ø 6/4):
 Fuses:
 Operating mode:
 Dimensions in mm (W x D x H):
 Weight in kg:

SI-923

220 – 240 V
 0.1 – 0.8 A
 ± 10 %
 50 – 60 Hz
 70 W
 5.5 Ncm
 approx. 100 ml/min
 2x 250 V – 1.25A slow-blow
 S3 (4min/10min)
 252 x 254 x 90
 3.30

SI-915

100 – 130 V
 0.2 – 1.6 A
 ± 10 %
 50 – 60 Hz
 70 W
 5.5 Ncm
 approx. 100 ml/min
 2x 250 V – 1.25A slow-blow
 S3 (4min/10min)
 252 x 254 x 90
 3.30

Classification according to § 5 of the General Specifications for the Safety of Medical Electrical Equipment according to IEC 60601-1 / UL 60601-1



Equipment of Protective Class II (type of protection against electric shock)



Type BF appliance (not suitable for intracardiac application)



Motor REF NB04720016 and foot control REF NB04491600 conform to Class AP according to IEC 60601-1 / UL 60601-1 in danger zone M.



The foot control is water-tight according to IPX8, 1m depth of immersion, 1 hour (water-tight according to IEC 60529)

Technical data

Physical characteristics

Temperature in storage:	-40 °C (-40 °F) to +70 °C (+158 °F)
Air humidity in storage:	8 % to 80 % (relative), non-condensing at +40 °C (+104 °F)
Temperature in operation:	+10 °C (+50 °F) to +40 °C (+104 °F)
Air humidity in operation:	15 % to 80 % (relative), non-condensing at +40 °C (+104 °F)

Recycling

W&H considers that it has a special duty towards the environment. The OsseoSet™ 200 equipment along with its packaging has been designed to be as environmentally friendly as possible.

Disposal of the OsseoSet™ 200 equipment

The equipment contains many valuable materials. Therefore return your equipment for material recycling via the relevant public collection system.

Disposal of the foot control

When the foot control is to be scrapped, it must be disposed of – if necessary – as “special electronic waste” in accordance with local regulations.

Disposal of the packaging material

All packaging materials have been selected according to environmentally compatible and disposal aspects and can be recycled. Please send old packaging materials to the relevant collection and reprocessing system. In this way, you will contribute to the recycling of raw materials and the avoidance of waste.



Letter of indemnity

This W&H product has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantee faultless operation. Please note that claims under warranty can only be validated when all the directions in the instructions for use have been followed.

As manufacturer, W&H is liable for material or manufacturing defects within a warranty period of one year from the date of purchase.

We accept no responsibility for damage caused by incorrect handling or by repairs carried out by third parties not authorized to do so by W&H! High-pressure bulbs are excluded from the warranty.

Claims under warranty – accompanied by proof of purchase – must be sent to the vendor or to an authorized W&H service point. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

year warranty

CERTIFICATION OF TRAINING

essential for EU user / customer

The user / customer has been trained in all functions of the surgical unit in accordance with current Instructions for Use. Particular attention was shown to Safety notes, Disinfecting, Cleaning, Sterilization and Servicing.

W&H Surgical unit _____

Type _____

SN _____

Name of the user / customer _____

Clinic, Department _____

Address _____

Signature _____

Name of the instructor _____

Address _____

Date _____

Signature _____



DENTALWERK

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CERTIFICATION OF TRAINING

essential for EU user / customer

The user / customer has been trained in all functions of the surgical unit in accordance with current Instructions for Use. Particular attention was shown to Safety notes, Disinfecting, Cleaning, Sterilization and Servicing.

W&H Surgical unit _____

Type _____ SN _____

Name of the user / customer _____

Clinic, Department _____

Address _____

Signature _____

Name of the instructor _____

Address _____

Date _____ Signature _____



Authorized W&H Service organizations

A

W&H Dentalmechanik GmbH, Ignaz-Glaser-Straße 60, A-5111 Bürmoos,
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GB

IRL

M

W&H (UK) LIMITED, 6 Stroud Wood Business Centre, Park Street, St. Albans, Herts AL2 2NJ,
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